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WILLIAM H. DIPPert
REED SMITH LLP
599 LEXINGTON AVENUE
29TH FLOOR
NEW YORK, NY 10022-7650

EXAMINER

PREBILIC, PAUL B

ART UNIT PAPER NUMBER

3738

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DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,172

Applicant(s)

GLOBERMAN ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-147 is/are pending in the application.
- 4a) Of the above claim(s) 126-147 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24, 27, 28, 30, 31, 34-49, 51-63, 65-68, 70, 75, 78-81, 84-86 and 89-125 is/are rejected.
- 7) ☒ Claim(s) 25, 26, 29, 32, 33, 50, 64, 69, 71-74, 76, 77, 82, 83, 87, and 88 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 30, 2004 has been entered.

Election/Restrictions

Newly submitted claims 126-147 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 126-147 are directed to a method of inserting the device that is independent and distinct from the originally filed and previously prosecuted invention of a spacer. For this reason, the claims are withdrawn from consideration; see MPEP 819 and 821.03, which are incorporated herein by reference.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 126-147 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The disclosure is objected to because of the following informalities:

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The continuing data attempts to claim priority to an application that after 4 months from the present filing date or 16 months from the date of a parent application. For this reason, it violates 37 CFR 1.78(a)(2)(ii). Reference to this application will have to be removed or evidence that reference to it was made in the required time period must be provided. Appropriate correction is required.

Claim 120 is objected to because of the following informalities:

On line 1 of claim 120, the language "an extensions" is grammatically awkward. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 113-115 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although support for axial dense regions can be found in the Figures 6T to 6V, the claimed ranges "on at least 40% of said body" and "at least 50% of the surface area" lack original support. For this reason, the Examiner asserts that these ranges constitute new matter with respect to the original disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 107-109 and 113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 107-109, the claim language is unclear because the tips as claimed should always be 100% of the contact surface as claimed because the tips are all that would contact a target vertebra. Rather, if applicant claimed that the spacer geometry had an outer surface such that the contact surface was a percentage of the outer surface, this would be clear.

With regard to claim 113, line 8, the claim language is unclear because "said body cross-section" should include the dense extension section cross-section. Therefore, it is unclear how the dense extension section cross-section can have a diameter twice that of the body cross-section.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-16, 19-24, 27, 28, 30, 31, 34, 35, 36, 41-44, 46, 48, 51-62, 64, 66, 68, 70, 78, 80, 81, 84, 86, 90-95, 103-115, and 120-125 are rejected under 35 U.S.C. 102(b) as being anticipated by Pisharodi (US 5,693,100). Pisharodi anticipates the claim language where the tube as claimed is shown in Figure 7 of Pisharodi (see also column 7, lines 27-37), the slits as claimed are between sections (34), the axial

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displaced extensions are the axial aligned legs of subunits (34,36), and the locking element is the screw (42) with locknut (40); see the figures, column 4, line 58 to column 5, line 46.

Regarding claim 9, the slits between the legs are perpendicular or not parallel to the longitudinal axis.

Regarding claim 11, slits along the axis are of a different length than the slit between the legs.

Regarding claim 30, Pisharodi has two segments along the longitudinal axis.

Regarding claims 56, 59, 64, and 113, the cross-section claimed can be taken at an angle across any part of the device such that the claim language is fully met to the extent it can be given patentable weight.

Regarding claims 104 and 105, since the diameter of expansion and be incrementally varied, it follows that small fractions over the unexpanded diameter are possible with Pisharodi's device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 37-40, 45, 47, 49, 63, 65, 67, 79, 85, 89, and 99-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 5,693,100) alone.

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Pisharodi meets the claim language but lacks curved slits (claim 5), a varied profile (claims 37, 38, 39, 40), unevenly distributed extensions (claims 45, 47, 49), elliptical cross-sectioned tube (claim 63), bent cross-sectioned tube (claim 65, 67), a twisted joint (claim 79), annealing (claim 85, 89), shape-memory materials (claims 96, 97), or axial deformed at certain loads (claims 98-102). However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to vary the structure of Pisharodi because Applicants have not disclosed that varied structures provide some advantage, are used for a particular purpose, or solve stated problems. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well only slight variations in shape of size are required or deformation could be made at loads over 20 Kg (it is noted that the claims do not preclude deformation at lower loads than those claimed in claims 98-102). Therefore, it would have been an obvious matter of design choice to modify Pisharodi to obtain the invention as specified in the claims.

Claims 17, 18, and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 5,693,100) in view of Pisharodi (US 5,123,926).

Regarding claims 17, 18 and 119, Pisharodi discloses an expandable spacer but lacks the teaching of spurs on the spacer as claim. Pisharodi teaches of an artificial spine prosthesis with spurs (Fig. 3, Ref. Num. 8) to hold the prosthesis within the intervertebral disk space. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Pisharodi to have spurs on the outside of the spacer to better hold it in place.

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Claims 116-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 5,693,100) in view of Stubstad et al (US 3,867,728). Pisharodi meets the claim language as explained above, but fails to teach a coating of bioactive material as claimed. However, Stubstad teaches that it was known to use bioactive coatings to improve or prevent ingrowth; see column 11, lines 39-65. Therefore, it is the Examiner's position that it would have been obvious to put a bioactive coating on Pisharodi's device for the same reasons that Stubstad does the same.

Response to Arguments

Applicant's arguments with respect to the pending claim have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 25, 26, 29, 32, 33, 50, 69, 71-77, 82, 83, 87, and 88 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilib whose telephone number is (703) 308-

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2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a stylized flourish at the end.

Paul Prebilic
Primary Examiner
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